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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,096	01/20/2004	Robert B. Raffa	ORTU-0007	2441

7590 05/10/2005

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EXAMINER	
JONES, DWAYNE C	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,096	RAFFA ET AL.	
	Examiner	Art Unit	
	Dwayne C. Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 16-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 16-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/15/4; 8/9/4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS of 8/26/4 and Protest Copy*.

Reissue Applications

Status of Claims

1. Claims 6 and 15-66 are pending.

2. Claims 6 and 15-66 are rejected.

3. Claims 1-5 and 7-17 are cancelled.

Protest

4. A third party protest has been filed in this reissue application and the proposed rejections are incorporated in this Office Action.

Reissue Amendment Format

5. Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b). In particular, new claims 16-66 fail to comply with 37 CFR 1.173(b) because the entire text must be completely underlined.

Information Disclosure Statement

6. The information disclosure statements of March 15, 2004; August 9, 2004; and August 26, 2004 have been reviewed and considered, see enclosed copies of PTO FORM 1449.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 6 and 15-66 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Flick et al. of U.S. Patent No. 3,652,589. Flick et al. teach of a composition containing tramadol and phenacetin In addition, Flick et al. additionally disclose that a synergistic effect is observed when tramadol is combined with other therapeutically active agents, (as cited from column 12, lines 45-51). Moreover, Flick et al. specifically teach of a tablet that contains tramadol and p-acetamino phenol, (refer to Example 23). Due to the facts that acetaminophen is the active metabolite of phenacetin as well as the fact that the FDA mandated that phenacetin containing products to be reformulated with acetaminophen in 1983, the prior art patent of Flick et al. clearly anticipates the instantly claimed subject matter of 10/761,096 (the reissue of U.S. Patent No. 5,336,691) through the inherent disclosure of the actual reduction to practice and administration of tramadol and phenacetin, a precursor compound to the active metabolite of acetaminophen, see *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

9. Claims 6 and 15-66 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Flick et al. of U.S. Patent No. 3,830,934. Flick et al. teach of a composition containing tramadol and phenacetin In addition, Flick et al. additionally disclose that a synergistic effect is observed when tramadol is combined with other therapeutically active agents, (as cited from column 12, lines 35-41). Moreover, Flick et al. specifically teach of a tablet that contains tramadol and p-acetamino phenol, (refer to

Example 23). Due to the facts that acetaminophen is the active metabolite of phenacetin as well as the fact that the FDA mandated that phenacetin containing products to be reformulated with acetaminophen in 1983, the prior art patent of Flick et al. clearly anticipates the instantly claimed subject matter of 10/761,096 (the reissue of U.S. Patent No. 5,336,691) through the inherent disclosure of the actual reduction to practice and administration of tramadol and phenacetin, a precursor compound to the active metabolite of acetaminophen, see *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 6 and 15-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flick et al. of U.S. Patent No. 3,652,589. Flick et al. teach of a composition containing tramadol and phenacetin In addition, Flick et al. additionally disclose that a synergistic effect is observed when tramadol is combined with other therapeutically active agents, (as cited from column 12, lines 45-51). Since the prior art patent teaches of a synergistic effect with tramadol and the precursor compound of acetaminophen, the various weight ratios that are instantly claimed are not unexpected results but rather expected results of the already previously stated synergy, as disclosed and specifically taught by Flick et al.

14. Moreover, Flick et al. specifically teach of a tablet that contains tramadol and p-acetamino phenol, (refer to Example 23). Due to the facts that acetaminophen is the active metabolite of phenacetin as well as the fact that the FDA mandated that phenacetin containing products to be reformulated with acetaminophen in 1983, the prior art patent of Flick et al. clearly anticipates the instantly claimed subject matter of 10/761,096 (the reissue of U.S. Patent No. 5,336,691) through the inherent disclosure of the actual reduction to practice and administration of tramadol and phenacetin, a precursor compound to the active metabolite of acetaminophen, see *Schering Corp. v.*

Geneva Pharm., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003). For these reasons one having ordinary skill in the art would have been motivated to use and administer the well-known compounds of tramadol along with acetaminophen (especially since phenacetin is the known precursor compound to its active metabolite of acetaminophen and also because Flick et al. teach of "[e]specially valuable combinations are those with other analgesics such as with . . . phenacetin, or the like", (see column 12, lines 49-51). Moreover, the skilled artisan would have been motivated to select and determine specific ratios of these two well-known compounds because the determination of a dosage having the optimum therapeutic index is well within the purview of one having ordinary skill in the art, and the artisan would be more than motivated to determine optimum amounts to get the maximum effect of the drug while minimizing the unwanted and/or adverse side effects.

15. Claims 6 and 15-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flick et al. of U.S. Patent No. 3,830,934. Flick et al. teach of a composition containing tramadol and phenacetin In addition, Flick et al. additionally disclose that a synergistic effect is observed when tramadol is combined with other therapeutically active agents, (as cited from column 12, lines 35-41). Since the prior art patent teaches of a synergistic effect with tramadol and the precursor compound of acetaminophen, the various weight ratios that are instantly claimed are not unexpected results but rather expected results of the already previously stated synergy, as disclosed and specifically taught by Flick et al.

16. Moreover, Flick et al. specifically teach of a tablet that contains tramadol and p-acetamino phenol, (refer to Example 23). Due to the facts that acetaminophen is the active metabolite of phenacetin as well as the fact that the FDA mandated that phenacetin containing products to be reformulated with acetaminophen in 1983, the prior art patent of Flick et al. clearly anticipates the instantly claimed subject matter of 10/761,096 (the reissue of U.S. Patent No. 5,336,691) through the inherent disclosure of the actual reduction to practice and administration of tramadol and phenacetin, a precursor compound to the active metabolite of acetaminophen, see *Schering Corp. v. Geneva Pharm., Inc.,* 339 F.3d 1373, 1377 (Fed. Cir. 2003). For these reasons one having ordinary skill in the art would have been motivated to use and administer the well-known compounds of tramadol along with acetaminophen (especially since phenacetin is the known precursor compound to its active metabolite of acetaminophen and also because Flick et al. teach of "[e]specially valuable combinations are those with other analgesics such as with . . . phenacetin, or the like", (see column 12, lines 39-41). Moreover, the skilled artisan would have been motivated to select and determine specific ratios of these two well-known compounds because the determination of a dosage having the optimum therapeutic index is well within the purview of one having ordinary skill in the art, and the artisan would be more than motivated to determine optimum amounts to get the maximum effect of the drug while minimizing the unwanted and/or adverse side effects.

17. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,336,691 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

18. Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

19. These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

20. While there is concurrent litigation related to this reissue application, action in this reissue application will NOT be stayed in view of applicant's request that the application be examined at this time. Due to the related litigation status of this reissue application, EXTENSIONS OF TIME UNDER THE PROVISIONS OF 37 CFR 1.136(a) WILL NOT BE PERMITTED.

21. In view of ongoing concurrent litigation the **PERIOD OF RESPONSE** for this Office Action on the merits, will be shortened to **2 MONTHS**.

22. As it is not clear whether Patent owner received a copy of the protest, a copy is included with this Office Action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-

0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

DWAYNE JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
April 6, 2005